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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,285	09/26/2001	Sven Enerback	13425-042001 / 00298-US	9639
26161	7590	02/12/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/963,285	Applicant(s) ENERBACK ET AL.	
	Examiner Nancy Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 35, drawn to an isolated human FOXC2 promoter region, recombinant construct comprising said promoter, vector comprising said construct, host cell comprising said construct, classified in class 536, subclass 24.1, 23.5, class 435, subclasses 320.1, 325, 252.3, 254.2.
- II. Claims 10-11, and 34, drawn to a method for identification of an agent regulating the human FOXC2 promoter activity, classified in class 435, subclass 6, .
- III. Claims 12-19, 35, drawn to an isolated human FOXC2 enhancer region, classified in class 536, subclass 24.1, 23.5, class 435, subclasses 320.1, 325, 252.3, 254.2.
- IV. Claims 20-21, and 34, drawn to a method for identification of an agent that regulates a human FOXC2 enhancer activity, classified in class 435, subclass 6.
- V. Claim 22, drawn to a method of identification of an agent that regulates a murine Fox C2 promoter, classified in class 435, subclass 6.
- VI. Claims 23 and 24, drawn to a method for identification of an agent that regulates the murine FoxC2 enhancer activity, classified in class 435, subclass 6.

- VII. Claim 25, 28-30 drawn to an isolated nucleic acid, vector containing nucleic acid which is SEQ ID NO:3 or complement thereof, variant nucleic acid which hybridizes thereto, or sequence which is degenerate as a result of the genetic code, vector comprising said nucleic acid molecule, or cell containing said vector, classified in class 536, subclass 23.1.
- VIII. Claims 26, 27, drawn to an isolated polypeptide encoded by SEQ ID NO:3 or complement thereof, variant nucleic acid which hybridizes thereto, or which is degenerate due to the genetic code, classified in class 530, subclass 350.
- IX. Claim 31, drawn to a method for producing a variant form of FOXC2 transcription factor polypeptide, classified in class 435, subclass 69.1.
- X. Claim 32, drawn to a method for identifying an agent that regulates expression of a FOXC2 transcription factor, classified in class 435, subclass 6.
- XI. Claim 33, drawn to an antisense oligonucleotide capable of hybridizing to nucleic acid of SEQ ID NO:3 or complement, or variant, classified in class 536, subclass 24.5.

Inventions of Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using, such as a probe in a method of hybridization.

Inventions of Group III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as a probe in a method of hybridization.

Inventions of Group VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used as a hybridization probe, and the product as claimed can be made by in vitro synthetic methods.

Inventions of Group IX and Group VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and

materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by in vitro synthetic methods.

The products of Group I, III, VII, VIII, and XI, are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups).

Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups II, IV-VI, IX and X are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II, IV-VI, IX and X comprise steps which are not required for or present in the methods of the other groups: contacting a candidate agent with the human FOXC2 promoter region (Group II), contacting a candidate agent with the human FOXC2 enhancer region (Group IV), contacting a murine FoxC2 promoter shown in SEQ ID NO:5 with a candidate agent and measuring expression (Group V), contacting a murine FoxC2 enhancer nucleotide sequence with a candidate agent and measuring expression (Group VI), culturing a host cell and recovering a polypeptide (Group IX), contacting a nucleic acid encoding a FOXC2 transcription factor with a candidate agent and determining expression (Group X). The end result of the methods are different: identification of an agent regulating the human FOXC2 promoter activity (Group II), identification of a human FOXC2 enhancer activity (Group IV), identification of an agent that regulates a murine FoxC2 promoter (Group V), identification of an agent that

regulates the murine FoxC2 enhancer (Group VI), production of a variant FOXC2 transcription factor polypeptide (Group IX), and identification of an agent that regulates expression of a FOXC2 transcription factor (Group X). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Except for the specific relationships described above, the inventions of Groups I, III, VII, VIII and XI, and Groups II, IV-VI, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different products of Groups I, III, VII, VIII and XI are not used in the methods of Groups II, IV-VI, IX and X, except as noted above.

Claim 34 link(s) inventions of Group II and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 34. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or

divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further more, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv


TERRY MCKELVEY
PRIMARY EXAMINER